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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAMELA R. CONTAG, DAVID A. BENARON,
and CHRISTOPHER H. CONTAG

Appeal 2012-001889
Application 08/844,336
Technology Center 1600

Before FRANCISCO C. PRATS, JEFFREY N. FREDMAN, and STEPHEN WALSH, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a biodetector. The Examiner rejected the claims as failing to satisfy the written description requirement. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

Statement of the Case

Background

The Specification teaches that "the biodetectors of the invention convert the binding to a target substance, *i. e*., a ligand, into a detectable signal" (Spec. 6, ll. 31-33).

The Claims

Claims 1, 5, 6, 9, 21, 22, and 25-27 are on appeal. Claim 1 is representative and reads as follows:

> 1. A biodetector for the detection of a selected substance comprising:
>
> (a) a transmembrane fusion protein comprising an extracellular ligand-specific moiety and a protein-modifying membrane intracellular enzymatic signal transforming domain, wherein the extracellular ligand-specific moiety comprises an antibody and wherein the antibody binds the selected substance, which binding activates the intracellular enzymatic signal transforming domain, wherein the membrane intracellular enzymatic signal transforming domain is a kinase;
>
> (b) a transducer protein, wherein the transducer has an inactive form and an active form which are distinct from each other, and the activated intracellular enzymatic signal transforming domain converts the inactive form of the transducer into the active form of the transducer protein, wherein the transducer and the intracellular enzymatic signal transforming domain are separate proteins;
>
> (c) a responsive element comprising a nucleic acid encoding a light-generating protein operably linked to a transcription activation element, wherein the responsive element is bound by and activated by the active form of the transducer, resulting in a detectable light signal.

The issue

The Examiner rejected claims 1, 5, 6, 9, 21, 22, and 25-27 under 35 U.S.C. § 112, first paragraph as failing to satisfy the written description requirement (Ans. 4-9).

The Examiner finds that the claims "encompass the mixing and matching of thousands of different prokaryotic and eukaryotic elements that must work together to form a functional biodetector. The single functional embodiment . . . utilizes bacterial elements and promoters in a bacterial biosensor" (Ans. 7). The Examiner finds that the "art is silent with regard to efficacy of using eukaryotic elements within a bacterial biosensor or vice versa" (Ans. 7). The Examiner finds that "a survey of the relevant art demonstrates an inability to introduce a complete eukaryotic signal transduction system in any bacterial cell" (Ans. 7). The Examiner finds that "the specification discloses that one has to screen for operative and inoperative embodiments at each level and provides no guidance as to what specific kinase would be functional in a given biodetector" (Ans. 7).

Appellants contend that the

> claims specify that the transmembrane fusion protein is made up of an antibody moiety (extracellular portion) and a kinase (intracellular portion). Binding of the ligand to the extracellular antibody moiety activates the intracellular kinase. The activated kinase activates the transducer (via transfer of a phosphate group from a donor, such as ADP or ATP, to an acceptor, typically to activate an enzyme) which binds to the promoter linked to the light-generating protein and regulates expression of the light-generating protein.

(App. Br. 5).

Appellants contend that "in the instant case, the antibody and kinase components of the chimeric transmembrane fusion protein which initiates a signal-transduction cascade intracellular are also well known" (App. Br. 9).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's finding that the disclosure of the Specification failed to demonstrate possession and descriptive support for Claim 1?

Findings of Fact

The following findings of fact ("FF") are supported by a preponderance of the evidence of record.

1. The Specification teaches that

> the biodetectors of the present invention comprise (1) a signal converting element, comprising an extracellular ligand-specific binding moiety, which is fused to an intracellular signal transforming domain which is capable of activating a (2) transducer component, which in its active form is capable of activating a (3) responsive element, such as a promoter which is operatively linked to a (4) reporter gene, encoding for a polypeptide with unique properties that are easily detected, for example optically. Thus, the biodetectors of the invention convert the binding to a target substance, *i. e.*, a ligand, into a detectable signal.

(Spec. 6, ll. 25-34).

2. The Specification teaches that "the ligand-binding domain is an antibody or a derivative thereof, including but not limited to polyclonal antibodies, monoclonal antibodies (mAbs), humanized or chimeric antibodies, single chain antibodies, Fab fragments, $F(ab')_2$ fragments, fragments produced by a Fab expression library, antiidiotypic

(anti-Id) antibodies, and epitope-binding fragments" (Spec. 15, ll. 10-14).

3. Claim 1 limits the "signal transforming domain" to a kinase.

4. The Specification teaches "the active domain of the bacterial phosphorylase, PhoQ, will be fused in a gene fusion to a region of a heavy chain antibody cDNA" (Spec. 15, ll. 34-36).

5. The Specification teaches that the "transducer may be any molecule that can recognize and respond to a change in conformation, electrical charge, addition or subtraction of any chemical subgroup, such as phosphorylation, glycosylation, and in turn is capable of triggering a detectable response" (Spec. 16, ll. 15-19).

6. The Specification teaches that "reporter genes may encode for enzymes that can cleave a color absorbing substrate such as β-lactamase, luminescent and fluorescent proteins, enzymes with fluorescent substrates, or any other gene that encodes an optically active chemical or that can convert substrate to an optically active compound" (Spec. 17, ll. 12-15).

Principles of Law

> [T]he hallmark of written description is disclosure…. [T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010).

Analysis

We are not persuaded that the Specification fails to adequately describe the biodetector as claimed. It is well settled that

> the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, "[t]he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment."

University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004).

Claim 1, as interpreted in light of the Specification, is broadly drawn to biodetectors composed of antibodies linked to kinases, which kinases are capable of modifying a transducer upon ligand binding to the antibody and where the transducer then induces transcription of a light generating protein. The Specification therefore must adequately describe that genus of compounds.

In this case, the Specification specifically lists antibody types which may function as ligand binding domains, including monoclonal antibodies which may be targeted to a specific ligand (FF 2). The Specification teaches the use of protein kinases as signal transforming domains and specifically teaches the phosphorylase PhoQ (FF 3-4). The Specification teaches transducers which, in the context of claim 1, are molecules which are modified by a kinase to activate a transcription activating element (FF 5). Finally, the Specification teaches a list of reporter genes (FF 6).

The present case is therefore most closely analogous to *Capon*. In *Capon*, the prior art provided the underlying information regarding the members of the genus. *Capon* teaches that the "Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes." *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005).

In the instant case, both the Specification and prior art teach several species for each component with which the claimed genus of compounds is constructed. As in *Capon*, where the molecular components needed to make a chimeric gene were known in the art, the evidence here supports a finding that molecular components needed for Appellants' biodetector were known in the art. Therefore, this situation is also unlike that in *Ariad*, where the invention was drawn to an NF-κb inhibitor of which there was only, at best, a single example disclosed. *See Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1356 (Fed. Cir. 2010).

The Examiner finds that "while the individual components of the instant invention may have been known in the art, the compatibility of said components which would give rise to a functional biodetector was not" (Ans. 12).

We are not persuaded. In every situation where patent claims encompass mixtures of generic components, the argument could be raised that not every combination of molecular components has been specifically analyzed by the patentee. However, "[i]t is not necessary that every permutation within a generally operable invention be effective in order for

an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention." *Capon*, 418 F.3d at 1359.

The arguments raised by the Examiner represent "enablement" type arguments, not "written description" issues. That is, the concern over whether the mixing and matching would work and the need to screen for operative embodiments represent enablement concerns and do not implicate written description. Appellants have broadly described a composition which may include any antibody, any kinase, any transducer which is responsive to the kinase and any reporter gene which may be induced by the transducer (FF 1-6). Consistent with *Capon*, this satisfies the written description inquiry.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that the disclosure of the Specification failed to demonstrate possession and descriptive support for Claim 1.

SUMMARY

In summary, we reverse the rejection of claims 1, 5, 6, 9, 21, 22, and 25-27 under 35 U.S.C. § 112, first paragraph as failing to satisfy the written description requirement.

REVERSED

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